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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,413	03/26/2004	Hsing-Wen Sung	S&T-134	3273
41648	7590	12/31/2007		
HOSHENG TU			EXAMINER	
15 RIEZ			KENNEDY, SHARON E	
NEWPORT BEACH, CA 92657-0116				
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			12/31/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,413	<b>Applicant(s)</b> SUNG ET AL.	
	<b>Examiner</b> Sharon E. Kennedy	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/12/2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,5,18 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,18 and 21 is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☒ Claim(s) 22-30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment has been carefully considered. However, new prior art is found which anticipates claim 3. This office action is being made non-final so that applicant can consider and respond to the new rejection.

### ***Claim Objections***

Claims 22-30 are objected to because of the following informalities: These claims contain typographical errors. "The" is spelled "Te". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 3 is are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Helmus, US 2003/0153972.

The examiner takes the position that the earliest effective filing date of applicant's claimed subject matter is March 26, 2004, the filing date of this application. The examiner has carefully examined applicant's related family patents for the subject

matter involving the shape memory biodegradable polymer and the at least two zones as stipulated. However, the examiner cannot locate a previous disclosure of this subject matter prior to March 26, 2004, or the filing date of this application. Accordingly, the examiner takes the position that the Helmus application qualifies as prior art under 35 U.S.C. 102(e).

Regarding claim 3, Helmus discloses biodegradable implantable stents which comprise two layers or "zones"-- a biodegradable inner, or core material, and a biodegradable coating or covering material, at least partially covering the inner material. See [0009] of the '972 reference. At least one of the core material and coating material comprises a biodegradable shape memory polymer. See [0014].

#### ***Allowable Subject Matter***

Claims 5, 18, 21 are allowed.

Claims 22-30 are objected to as containing minor informalities, but would be allowed if corrected. See the above objection to claims 22-30.

The following is a statement of reasons for the indication of allowable subject matter: None of the prior art shows or suggests the drug lipostabil incorporated into a stent delivery device in the manner claimed. Regarding claims 5+, this claim requires the genipin crosslinking agent with the particular therapeutic zones. None of the prior art suggests the genipin agent with the particular stent as used.

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***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Sharon E. Kennedy/*  
Sharon E. Kennedy  
Primary Examiner  
Art Unit 1615